

Contour XT blood glucose meter

Summary from an evaluation under the direction of SKUP Report SKUP/2012/94



Background

Contour XT is a new blood glucose meter produced by Bayer HealthCare.

The aim of the evaluation was to

- assess the analytical quality under standardised and optimal conditions (hospital environment)
- assess the analytical quality by the intended users
- compare the analytical quality among diabetes patients with and without a training program
- examine the variation between three lots of test strips
- examine if haematocrit interferes with the measurements
- evaluate the user-friendliness of Contour XT and the user guide

Materials and methods

A total of 83 diabetes patients took part in the evaluation. The participants were randomly divided into two groups. The “training group” received personal training in how to use the device, and the “mail group” received the device and instructions by mail. Both groups used the device for approximately two weeks at home, before they attended for an end-meeting.

Results

- The quality goal for imprecision was fulfilled. The repeatability CV obtained by the biomedical laboratory scientists was between 1,8 and 3,3%. The repeatability CV obtained by the diabetes patients was between 1,5 and 4,2%. The diabetes patients performed the measurements with approximately the same good precision, regardless of being trained or not
- Contour XT showed glucose results in agreement with the comparison method for glucose concentrations ≥ 10 mmol/L. For glucose concentrations < 10 mmol/L Contour XT gave systematically higher results than the comparison method. The bias was small (approximately 0,25 mmol/L), but statistically significant
- The accuracy of Contour XT was good. 100% of the results obtained by the biomedical laboratory scientists as well as by the diabetes patients were inside the accuracy quality limits in ISO 15197 (2003)
- All three lots of test strips used in the evaluation gave significantly higher glucose results than the results achieved with the comparison method. The deviation was small, but statistically significant
- Glucose measurements on Contour XT were not affected by haematocrit (range 34 – 49%)
- The diabetes patients were satisfied with the meter, the test strips and the user guide
- The fraction of technical errors was $< 2\%$, and the quality goal was fulfilled

Conclusion

The precision and the accuracy were good. The accuracy quality goal set in ISO 15197 was fulfilled. The user-friendliness of Contour XT and the user guide were assessed as satisfactory.

Comments from Bayer

A letter with comments from Bayer AS is attached to the report.

The complete report is found at www.skup.nu.